REMARKS

In the Office Action, the Examiner made final the rejection of Claims 38-50 under 35 U.S.C. §103(a) as being unpatentable over the combined disclosures of U.S. Patent No. 6,270,805 to Chen et al. ("Chen") in view of U.S. Patent No. 5,133,974 to Paradissis et al. ("Paradissis"). In response, Applicants respectfully request reconsideration and removal of this ground of rejection.

More particularly, Applicants aver that Chen cannot constitute prior art under 35 U.S.C. §102(b) because Chen was published on August 7, 2001; the present application was filed less than one year later on February 8, 2002.[1] Therefore, Chen can only constitute prior under 35 U.S.C. §102(e), and thus may be removed as a §103 prior art reference as per §103(c). Applicants respectfully aver that Chen is not a proper prior art reference because both Chen and the present application share two inventors in common (*i.e.*, Chih-Ming Chen and Xiu Xiu Cheng). Additionally, both applications were subject to assignment to Andrx Pharmaceuticals, Inc. In this regard, Applicants respectfully direct the Examiner's attention to the assignment recorded on January 12, 1999 at reel/frame 009691/0282, which assigned the Chen patent from the inventors to Andrx Pharmaceuticals, Inc. Applicants also respectfully direct the Examiner's attention to the assignment recorded on May 31, 2002 at reel/frame 012947/0082, which assigned the present application from the inventors to Andrx Pharmaceuticals, Inc.[2]

Applicants note that during prosecution of U.S. Serial No. 11/069,435, which claims priority to the present application, the Chen reference was also raised as prior art. *See* April 30, 2007 Office Action at pp. 4-5 in U.S. Serial No. 11/069,435. On December 31, 2007, the

[1] Additionally, the present application claims priority to Provisional Appl'n Ser. Nos. 60/267,456 and 60/267,457, both of which were filed on February 8, 2001, approximately six months *before* Chen was published.

[2] Applicants note that both Chen and the present application were subsequently assigned to Andrx Pharmaceuticals, LLC due to a merger.

Examiner acknowledged that Chen "share[s] the same assignee as the instant application[3] and do[es] not qualify as prior art." *See* December 31, 2007 Office Action at p. 5 in U.S. Serial No. 11/069,435.

Notwithstanding, even if Chen were a proper prior art reference (which Applicants do not concede), one of skill in the art would not find it obvious to combine Chen with Paradissis in order to create that which is claimed as the invention. More particularly, the combination of Chen and Paradissis would not lead one of skill in the art to the specific pharmacokinetic parameters recited in independent Claim 38 (and, therefore, in dependent Claims 39-50). In this regard, Chen does not provide any blood plasma data for bupropion (the only blood plasma data provided by Chen relates to diltiazem, an active ingredient unrelated to bupropion).[4] Paradissis does not cure this deficiency because it also does not provide any blood plasma data for bupropion.[5]

Additionally, one of skill in the art would also know that diltiazem and bupropion are very different drugs that have different routes of activity. Diltiazem is a calcium channel blocker used mainly for hypertension which acts by inhibiting the CYP3A4 enzyme. *See*, e.g., U.S. Patent No. 6,761,895 at Col. 10, lines 15-35 ("...diltiazem...are drugs that are metabolized by CYP3A4 and drugs that inhibit CYP3A4..."). In contrast, bupropion is an aminoketone-derivative that appears to be primarily involved with noradrenergic pathways and/or dopaminergic effects. *See* present Published Application at ¶¶ [0003] – [0004]. Because diltiazem and bupropion are very different drugs that do not act on the same pathways, one of skill in the art would realize that it would be impossible to predict useful blood plasma profiles for bupropion based on known blood plasma profiles for diltiazem. Applicants also note that

[3] That is, U.S. Serial No. 11/069,435, which is a divisional application of the present application.
[4] In fact, Chen makes only one passing reference to bupropion at Col. 3, lines 5-6.
[5] Paradissis does not specifically disclose the use of bupropion at all.

Chen's blood plasma profiles are derived from formulations that do not contain an immediate release layer; there is no teaching in Chen regarding what blood plasma profiles would be useful or expected in a formulation containing an immediate release component.

Based on the above, even if Chen were a proper prior art reference (which Applicants do no concede), Applicants respectfully request removal of this ground of rejection.

As per MPEP §706.07(f)(C)(1) and/or (2), Applicants respectfully request entry of the present submission because it places the application in condition for allowance and is being submitted less than two months from the June 19, 2009 mailing date of the Office Action.

In light of the foregoing remarks, Applicants respectfully submit that the claims of the present application are in proper form for allowance. Early and favorable consideration is therefore earnestly solicited and respectfully requested. If the Examiner does not believe the pending claims are in proper form for allowance, Applicants invite the Examiner to call the undersigned to discuss ways to further expedite prosecution of this application.

Respectfully submitted,

/matthew j. solow/

Matthew J. Solow
Reg. No. 56,878

MAILING ADDRESS
Hedman & Costigan, P.C.
1185 Avenue of the Americas
New York, NY 10036
(212) 302-8989